REMARKS

Prior to this Response, a Final Office Action rejecting all claims was mailed July 14, 2006, responding to Applicant's amendments and arguments made in response to a prior Office Action mailed September 7, 2005. Applicant filed a Request for Continued Examination January 12, 2007, submitting amendments to the claims and an affidavit from the inventor Dr. Will. Examiner rejected the amended claims in an Office Action dated April 11, 2007. Applicant timely filed a Notice of Appeal and timely submitted an Appeal Brief. The Appeal is now pending. Applicant hereby withdraws the current appeal and submits this RCE in order to submit new evidence into the record which, Applicant believes, addresses Examiner's rejections and places the Application in a condition for allowance.

In the last Office Action, dated April 11, 2007:

Claims 1-22 were rejected under 35 USC § 112 as indefinite in using the term "convex" in other than its ordinary meaning without giving an explicit differing definition;

Claim 22 was rejected under 35 USC § 112 as indefinite in relation to the recitation of "low profile";

Claims 1, 11, and 12 were finally rejected under 35 U.S.C. § 103(a) as unpatentable over EP 0372127A1 to L'Esperance or US 6,042,594 to Hellenkamp.

Claims 2 and 13 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US

4,173,980 to Curtin.

Claims 3-10 and 14-21 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US 5,591,174 to Clark et al;

Claims 3-10 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, and Curtin, in combination with Clark;

Claims 5-10, 17, and 20-22 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with Curtin and Clark, and further in combination with Olson US 6,613,061 to Olson et al.

In this Response, regarding the Claims, all rejections are respectfully traversed, and Applicant requests continued examination to consider new evidence in the form of a new Affidavit made under C.F.R. 1.132, new references in support of the new Affidavit and the previous Affidavit of Dr. Will, already of record, and new argument addressing the Affidavit and responsive to Examiner's rejection.

No amendment made was related to the statutory requirements of patentability unless expressly stated herein. No amendment made was for the purpose of narrowing the scope of any claim, unless Applicant has argued herein that such amendment was made to distinguish over a particular reference or combination of references.

Claims 1-22 are now pending in the present application. Reconsideration is requested. In addition to the new evidence the Applicant makes the following

remarks regarding individual issues:

THE APPLICANT'S TIME TO RESPOND

The last Office Action was mailed on April 11, 2007. Applicant timely filed a Notice of Appeal and Appeal Brief. Examiner rejected Applicant's Appeal Brief, arguing that the article presented in the Evidence Appendix was not properly entered in the record prior, with a Notice of Non-compliant Brief mailed on March 13, 2008, giving a one-month reply period which ended on April 14, 2008, due to the one-month period ending on a Sunday. In determining whether this document is timely filed, the Patent Office is asked to note the Applicant's Certificate of Mailing in conjunction with 37 CFR § 1.8.

THE SECTION 112 REJECTION

A. Claims 1-22: The term "convex" is clearly understood.

Examiner rejected claims 1-22 under § 112 second paragraph stating that Applicant has misused the term "convex." As an initial matter, Examiner never raised issue with this term in the prosecution of the application until after Applicant's submission of the RCE with accompanying amendment, so Applicant submits the use of the term is clearly understood. Examiner's dictionary definition of "convex" is correct, but the issue raised by Examiner is simply one of orientation – a convex surface may be considered concave from the reverse perspective so they are not mutually exclusive. The eyeball is essentially a ball – not perfectly spherical – i.e. convex. The eye fixation apparatus described in the application includes an "annular convex bottom contact portion" – i.e. annular to include an opening for access by a surgeon, and convex to match the convex

contours of the eyeball. It necessarily follows that the inside of a convex annulus will be concave – it is merely a matter of reference point. So reference to convex in this context, with reference to an eyeball, the Specification, the drawings, and the knowledge of a person of ordinary skill in the art, obviously would understand that one could refer to the overall shape as convex or concave and render the same meaning. As the Examiner has never before raised this issue and has exchanged numerous discourses with Applicant via office actions without confusion, Applicant submits that "convex" as used in the Specification, Drawings and Claims is clear.

B. <u>Claim 22: "Low profile" is clearly understood.</u>

Examiner rejected claim 22 under § 112 second paragraph stating that "low profile" is unclear as the total height of the device, including the X-Y translation guide members, would be too high to fit under an eyelid. Applicant submits the Examiner misreads the claim. It is the "eye fixation portion" which specifically includes the "low profile... substantially narrow so as to fit under the eye lid of a patient without the use of a lid speculum." Clearly Applicant is not claiming that the entire device fits under a patient's eyelid, but merely the portion extending outward with the criss-cross vacuum channels. Examiner's reference to Fig. 4 ignores the fact that such drawings and figures are not to scale but are necessarily distorted to enable reference to particular features. The Examiner's measurements of the figures provided is therefore inappropriate.

The need for a lid speculum is obviated in the present invention because the vacuum channel portion, which is what grips the surface of the eyeball, does

not require a hollow annulus above that portion in order to distribute vacuum along the surface area contacting the eye. This allows the eyelids to close to a degree over this thin lip, shown as # 14, in Fig. 4. The central open portion of the annulus which provides the access for surgical instruments and additional elements such as the translation guide members and docking screws, is sized to accept the surgical apparatus – which is essentially fixed. Prior art devices, such as L'Esperance (*see Fig. 1*), Hellenkamp (*see Fig. 2*) and Curtin (*see Fig. 2*), cited by Examiner under 103(a) rejections, require a vertical vacuum annulus over the contact area as well as the central vertical annulus providing surgical access. It is this vacuum annulus of prior art devices which is eliminated by the use of criss-cross channels which can extend laterally through a thin extending lip. Applicant made this clear through the Specification, and more so through his affidavit which described in detail the problems caused by prior art devices and how the present invention solves these problems through the use of low profile criss-cross channels.

Antecedent bases are provided in the original specification

(1) at p. 3 ll. 8-10 describing the need for a "low profile fit[ting] comfortably under the eye lid;

(2) at p. 4 ll. 12-14 describing an advantage of the present device as being low profile and not requiring need for a lid speculum, thereby distinguishing the present invention from existing devices.

Section 112 paragraph 2 requires the claims to be sufficiently clear to enable a person to understand, in light of the Specification and Drawings, what

the applicant regards as the invention. This does not impose a requirement to provide detailed dimensions, but allows the use of relative dimensions or references, so long as they are adequately clear. The use of language such as "substantially narrow" in relation to a reference which provides basis by which a person of ordinary skill in the art can understand the structure as in "so as to fit under the eye lid of a patient without the use of a lid speculum" is sufficiently clear. *See* Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed. Cir. 1986) ("A decision on whether a claim is invalid under § 112, 2d ¶, requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.") Applicant submits that the claim, read in light of the specification and drawings, with the knowledge of a person of ordinary skill in the art, is clear and definite and has proper antecedent basis.

THE SECTION 103(A) OBVIOUSNESS REJECTIONS

The Examiner rejected Claims 1, 11, and 12 under 35 U.S.C. § 103(a) as being unpatentable over L'Esperance or Hellenkamp, and further in view of U.S. Patent 5,133,726 to Ruiz (incorporated by reference in Hellenkamp). Claims 2 and 13 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, combined with US 4,173,980 to Curtin. Claims 3-10 and 14-21 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, combined with US 5,591,174 to Clark, et al. Claims 3-10 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, and Curtin, combined with Clark. Claims 5-10, 17, and 20-22 were rejected under § 103(a) as

unpatentable over L'Esperance or Hellenkamp, in combination with Curtin and Clark, and further in combination with Olson US 6,613,061 to Olson et al.

The standard under Section 103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. In re O'Farrell, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR Int'l v. Teleflex, Inc., 127 S.Ct. 1727, 1742, 167 L.Ed.2d 705 (2007). The Examiner bears the initial burden in the case of Section 103(a) obviousness rejection which requires the Examiner to put forward evidence that the invention as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention. In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) , citing In re Warner, 379 F.2d 1011, 1016 (CCPA 1967). Where the Examiner relies on a single prior art reference for an obviousness rejection, which does not describe every limitation of the claim, the Examiner must demonstrate how a person of ordinary skill in the art would have been motivated to modify the reference to achieve the invention without the benefit of hindsight, just as with a combination of references.

Where an Applicant submits evidence an Examiner cannot simply deny such evidence without citation to reference of submission of an affidavit himself detailing the bases of his knowledge and expertise. MPEP 2142; In re Mayne, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997). Although the Supreme Court rejected rigid application of the "suggestion, motivation, teaching test" applied by

courts in the past, it can still be a useful starting point for evaluation and to prevent hindsight analysis, so long as it is not applied rigidly and the evaluator maintains the framework of the analysis laid down in Graham v. John Deere Co., 383 U.S. 1 (1966). KSR, 127 S.Ct. at 1242. Moreover, the Examiner cannot rely on the applicant's disclosure in any way in making this prima facie case. MPEP 2143. The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. at 17-18; Miles Lab., Inc. v. Shandon Inc., 27 USPQ2d 1123, 1128 (Fed. Cir. 1993). Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness. Stratoflex, Inc. v. Aeroquip Corp., 218 USPQ 231, 236 (Fed. Cir. 1983). Each obviousness determination rests on its own facts. In re Durden, 226 USPQ 359, 361 (Fed. Cir. 1985).

"It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 230 USPQ 416 (Fed. Cir. 1986). Here, the Examiner relies upon conclusory statements that combining the references "would be obvious to one of ordinary skill in the art." The Examiner thus failed to establish a *prima facie* case of obviousness to support rejection.

Further, regarding all of the § 103(a) rejections, the Examiner failed to

make specific findings as to the level of ordinary skill and the differences between the prior art and the claimed invention.

The difference between the prior art and the invention is exactly that which is claimed and pointed out in the present application. Prior art solutions to the problem of fixing a patient's eyeball are also pathways to damage the patient's eye and can lead to less than optimal outcomes. The present invention focuses on solving these problems in a manner that goes against the conventional wisdom.

Applicant respectfully reasserts his previous traversal regarding these rejections, and directs the Examiner to both the previous affidavit and the newly submitted affidavit of Dr. Brian Will (hereinafter referred to as the First Will Affidavit and the Second Will Affidavit, respectively) with attached references, and arguments below.

Examiner's response to the First Will Affidavit

In the previous Office Action the Examiner responded to Dr. Will's Affidavit dated January 10, 2007. (Note, for ease of reference, Dr. Will's January 10, 2007 affidavit will be referred to as the *First Will Aff.*, and Dr. Will's April 15, 2008 affidavit accompanying this RCE will be referred to as the *Second Will Aff.*) Applicant addresses Examiner's point-by-point response here..

Examiner stated at page 2: "It is also noted that affiant makes reference to the opinions of others, who are not signatories to the affidavit. As such, the opinions of these others are of little moment." Dr. Will refers to the experience of himself and his staff of two other ophthalmologists. *See First Will Affidavit* ¶¶2 &

11. These are doctors that Dr. Will directly supervises in ophthalmologic surgical procedures, including LASIK procedures. *See Second Will Affidaft* ¶¶ *4*. As such, Dr. Will's statements regarding the experience of his staff should be given significant weight as it is an indication of the collective experience of his staff.

Examiner states at p.3 that, "It is presumed, but nowhere explicitly stated that the affidavit is directed to a device such as claimed in the instant claims..." Examiner is requested to reconsider the Affidavit, as it clearly references both specific elements of specific claims, and provides specific comparisons to the prior art cited by Examiner.

Examiner stated at p. 3 that the First Will Affidavit discussion was directed to a device Hellenkamp described as prior art. A thorough reading of the First Will Affidavit makes clear that it is directed to the device taught by Hellenkamp. See First Will Affidavit ¶¶4-5 & 5h, discussing displacement into the vacuum chamber of Hellenkamp and the function of the alternating lands and channels of the present invention in preventing such displacement. See also Hellenkamp at col.3, lines 20-61. Dr. Will was clearly discussing Hellenkamp's use of a disposable vacuum insert ring, not merely the prior art empty vacuum ring, and found that the solution taught by Hellenkamp - the insert ring - did not adequately address the problems of occlusion and scleral damage because it still contemplated significant displacement of scleral tissue into the vacuum ring - leading to chemosis. See Hellenkamp col.3, lines 20-61.

Examiner stated that L'Esperence would seem to achieve the same advantage of distributing vacuum contact over a larger surface area. This part is

true, however, L'Esperence does not achieve the same results as the present invention and comes with significant disadvantages that are avoided by the present invention. First, the porous membrane is subject to clogging. See First Will Affidavit ¶ and Second Will Affidavit ¶ . This clogging leads to the alternative dangers - loss of vacuum during the procedure; or creation of an unbreakable vacuum seal against the corneal surface which would cause damage when removed. The criss-cross channels avoid these dangers - by providing alternate non-occluded channels to as to maintain vacuum and also to provide open channels to break vacuum when the procedure is completed. As Dr. Will explained in detail, it is the alternating lands and grooves of the criss-cross channels that achieve this goal. This is different from L'Esperance and different from Hellenkamp, and not contemplated by either. Even combining the two references would not achieve the present invention's results.

Examiner states at p.4, "with regard to (c) ["markedly reduces deformation of the eye"]... no particular structure is theorized..." Examiner is directed to pages 6-7 of the Specification; First Will Affidavit ¶¶ 4(c) and 5(c)-(g).

Examiner states at p.4 that neither Hellenkamp nor L'Esperence provide a "vacuum anulus" either. This is incorrect. Hellenkamp includes a vacuum ring (Fig. 1, R) with an anular vacuum chamber (P, see also Figs. 4&5, #42 and the volume indicated between insert 50 and the surface of the eye). The anular vacuum volume of the ring is the "vacuum anulus". In L'Esperence the vacuum anulus is indicated by the vacuum chamber rising above porous membrane 11 (see L'Esperence Fig. 1).

Examiner states at p.4 that "regarding (e) [device is repositionable because the scleral tissue is not significantly displaced into the vacuum anulus] the devices L'Esperence... and Helenkamp do not provide vacuum through an unobstructed anulus, they too would exhibit this advantage." Respectfully, the First Will Affidavit explains in detail the problems relating to the damage caused by drawing the scleral tissue into the vacuum anulus (i.e. the vacuum chamber) of Hellenkamp. See First Will Affidavit ¶5. The vacuum ring can cause damage which prevents re-positioning due to swelling. L'Esperence - if the porous membrane clogs and causes a vacuum lock on the corneal surface - can also damage the eye preventing repositioning. This does not necessarily happen in every case, but it is a problem, which Dr. Will attests that he has encountered in his practice. The criss-cross channel design alleviates this problem and allows repositioning - reliably and without significant risk of scleral displacement. The alternating lands and grooves, and shallow channels, minimize displacement of scleral tissue into the channels and the alternate vacuum paths (and therefore, alternate vacuum breaking paths) prevent the danger of vacuum lock present if the porous surfaces of L'Esperence clog.

Examiner states at pp.5-6 that Hellenkamp's vacuum insert prevents the distortion of the eyeball that Dr. Will's invention seeks to prevent. This is incorrect. See Second Will Affidavit, ¶¶8 & 18. Conventional vacuum rings, such as Hellenkamp, are designed to draw the eyeball into the center opening - causing it to bulge upwards and raise intraocular pressure (IOP) - in order to create a more tensioned corneal surface for cutting the keratome flap. The

present Application seeks to maintain as much as possible the natural shape of the eyeball (and therefore not raise IOP nor tension the corneal surface) - by utilizing a convex-shaped device which more closely matches the curvature of the eyeball and distributing vacuum over this convex form (convex meaning, as is clear from reading the claims in light of the Specification and Drawings, matching the convex curvature of the cornea). Reference to Ruize Fig. 10 indicates the "bulge" of the cornea which is the conventional wisdom in all of the prior art references.

Examiner states at pp.6-7 that it is not clear why other devices would require a lid speculum. Examiner is directed to the First Will Affdiavit ¶¶4-9. The Second Will Affidavit provides further explanation and references.

Examiner states at p. 7-8 that the L'Esperence device would have the same low profile as the Applicant's Claims. This is incorrect. The vacuum chamber volume of the L'Esperence device necessarily lies above the porous membrane (11) providing the vacuum grip. The low profile lip of L'Esperence that Examiner refers to actually begins where the low profile vacuum footprint of the present invention ends. Referring to the Application, Figs. 3&4, the outer diameter of the vertical portion of eye fixation appartus 12 in the present Application correpsonds approximately to the inner diameter of diameter of L'Esperence's vacuum chamber 10, such that L'Esperence's vertical chamber above membrane 11 is eliminated.

<u>New Evidence</u>

The Second Will Affidavit includes new evidence and new references for

consideration. The Second Will Affidavit specifically addresses the Examiner's skepticism about the need for lid specula when using devices incorporating the teachings of L'Esperence and Hellenkamp, and the problems caused by lid specula. See Second Will Affidavit ¶¶ 14-17. Exhibits 1-6 to the Second Will Affidavit are articles from peer reviewed journals. The references provide support for Dr. Will's assertion that conventional suction rings - which are as described in Hellenkamp, Curtin, Clark, and Olson - do cause damage to the eye. The source of the damage, according to the authors, is likely due to the displacement of the sclera into the vacuum anulus as well as the rise in intraocular pressure (IOP) during the application of suction. The present Application identifies reducing both of these pathways of damage as express objects of the invention. *See Specification "Summary and Advantages"; "Detailed Description."*

The new evidence also addresses a separate issue about which the Examiner has expressed skepticism. The references teach that deforming the eyeball and increasing IOP is desireable in order to tension the cornea for cutting the keratome flap. A basic goal and operating principle of using the criss-cross channels with a conforming surface is to minimize deformation of the eyeball and thereby avoid a damaging rise in IOP. In other words, the present Application teaches an opposite approach – to improve the accuracy of flap cuts and corneal shaping by minimizing the increase in IOP during the vacuum fixation and flap cutting portion of the procedure. As I have explained previously, the present apparatus and methods seek to achieve higher accuracy by reducing distortion of

the eyeball and changes in hydration of the cornea caused by suction rings such as described in Hellenkamp. Thus, the references cited by the Examiner actually teach away from the apparatus and methods which I am claiming.

A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 45 USPQ2d 1977 (Fed. Cir. 1998). In effect, "teaching away" is a more pointed and probative form of skepticism expressed in the prior art. Id. Teaching away from the prior art supports a conclusion of nonobviousness. The Dow Chemical Co. v. U.S.,18 USPQ2d 1657 (Cl. Ct. 1990). In this case it is clear that the conventional wisdom requires raising IOP for cutting the flap prior to the laser procedure. Dr. Will's Application takes an opposite approach - the use of criss-cross channels and a low-profile device conforming more closely to the natural shape of the eyeball are specifically intended to minimize rise in IOP during the flap cutting procedure. See Specification, "Background" & "Summary and Advantages"; "Detailed Description" pp.6-8. This is strong evidence that the claimed invention is non-obvious.

Claims 1, 11, and 12

The Examiner rejected Claim 1, 11 and 12 as unpatentable over L'Esperance or Hellenkamp. The combination of L'Esperance and Hellenkamp does not disclose the combinations of elements recited in independent Claims 1,

11 and 12, nor has any reference been asserted teaching or suggesting such modification, and therefore the Examiner has not established a *prima facie* case of obviousness. None of the references discloses apparatus or methods for an eye fixation apparatus utilizing criss-crossing channels on a convex bottom contact portion, without use of a vacuum annulus, nor do they disclose apparatus or methods capable of repositioning a vacuum-based eye fixation apparatus after vacuum has been applied initially. Nor has the Examiner identified any suggestion, teaching or motivation to modify the cited references to achieve Applicant's inventions other than Applicant's own disclosure, which is considered impermissible hindsight.

None of the references cited by Examiner teach, suggest, or disclose in any way the use of criss-crossing channels to apply vacuum. Thus, Examiner has not even presented a *prima facie* case of obviousness. Nor has Examiner cited any basis for the conclusion that a person of ordinary skill in the art would seek to modify the cited references to eliminate the vacuum annulus designs of the references, other than to argue that the prior art works just as well as Applicant's invention. This is in spite of the First Will Affidavit providing detailed recitations of the problems caused by prior art devices such as those described by L'Esperance and Hellenkamp. The Examiner has not provided a reference to bridge the critical gap between the use of a hollow vacuum annulus and the use of criss-crossing vacuum channels. Reference to the First and Second Will Affidavits provides explanation of the unique features of the present invention, and the significant differences from the prior art cited by the Examiner, and the

longstanding need for the invention.

Examiner states that both L'Esperance and Hellenkamp teach the device as claimed "except for the criss-cross channels" and use of such channels is obvious because "this is another configuration that would serve to distribute vacuum and thus provides no unexpected results." The Examiner went on to say that to "discontinue the vacuum and reposition the apparatus" is also obvious. With all do respect, this is the epitome of hindsight and requires the Examiner to completely disregard the Applicant's affidavit. Applicant explained, in detail, based upon years of experience and thousands of procedures, and a thorough knowledge of prior art devices, that apparatus using the annular vacuum rings of Hellenkamp or the annular chamber and porous membrane of L'Esperence, prevent the discontinuance of vacuum and repositioning of the fixation apparatus. The Examiner simply discounted the Applicants submission without citation to any reference nor any affidavit by the Examiner.

The references L'Esperance and Hellenkamp do not disclose the combinations of elements recited in independent Claims 1, 11 and 12, nor has any reference been asserted teaching or suggesting such modification, and therefore the Examiner has not established a *prima facie* case of obviousness. None of the references discloses apparatus or methods for an eye fixation apparatus utilizing *criss-crossing channels* on a convex bottom contact portion, without use of a vacuum annulus, nor do they disclose apparatus or methods capable of repositioning a vacuum-based eye fixation apparatus after vacuum has been applied initially, without damage to the ocular surface. In fact, none of

the references cited by Examiner disclose use of criss-cross channels at all. It is the use of criss-cross channels which primarily distinguishes claims 1, 11 and 12 over Examiner's cited references.

The Examiner provides no basis for disputing Applicant's description of the cited references' weaknesses, other than to argue that the prior art patents are "presumed valid" so Applicant's invention cannot be an unobvious advance. Applicant has never argued that Examiner's references are invalid, merely that they do not address or soive the problems solved by Applicant's inventions. Reference to First Will Affidavit provides explanation of the unique features of the present invention, and the significant differences from the prior art cited by the Examiner. Nowhere does the Examiner cite any reference upon which to base his conclusory statements that Dr. Will is incorrect, or that prior art devices work so well that no subsequent improvements in the art are necessary.

L'Esperance discloses a method and apparatus for modulating the flux distribution onto a surface to be profiled of an ablative radiation beam, including a fixation device which uses a porous membrane backed by a hollow vacuum annulus. *See L'Esperance, Fig. 1 and col. 4, ll. 28-34* (describing "a hollow annulus.") L'Esperance does not focus on the fixation apparatus but rather on the laser ablation apparatus and methods, especially lensing methods. The description of the fixation means is simply a "hollow annulus, having a convergent axial end wall 11 of air-permeable material contoured to engage and retain an eye via a scleral-corneal region." A porous membrane is significantly different from a criss-crsoss channels.

L'Esperance does not disclose using criss-cross channels for distributing vacuum, nor any means for fixation not requiring "a hollow annulus." L'Esperance does not even address the problems of scleral damage caused by vacuum fixation devices. Therefore, L'Esperance does not render Applicant's solution obvious.

The Hellenkamp reference, cited by Examiner, specifically discusses the problem of mucus accumulation which can occlude vacuum components, during procedures and after hardening, and which requires special cleaning procedures to remove. *See Affidavit of Dr. Will ¶ 5.h.* The removable vacuum member in Hellenkamp is specifically intended as an attempt to address this problem, among others, but it is an incomplete solution at best. *See Hellenkamp, col. 5, ll. 43-5.* Examiner states in his last Office Action, "Applicant then states the 'criss-cross channels, providing alternating lands grooves, are fundamental to the present invention', however, there has been no showing of the criticality of this particular arrangement of voids and barriers." *OA April 11, 2007 at p.10.* Applicant submits that this is the focus of much of the application itself – indeed it is one of the stated advantages over existing devices. Moreover, the First and Second Will Affidavits discuss in detail the differences, and resulting advantages, of his criss-cross channels over existing devices such as L'Esperance and Hellenkamp in detail.

Hellenkamp discloses an eye fixation apparatus utilizing an annular hollow vacuum ring with a vacuum ring insert to prevent complete occlusion of vacuum caused by chemosis or buildup of mucous in the vacuum ring. The vacuum ring

insert simply is intended to prevent complete occlusion, not prevent damage such as chemosis. *Hellenkamp col. 5 ll. 25-30* ("to maintain the suction channel evacuated *even in the presence of chemosis*") (emphasis added). Thus Hellenkamp does not solve the problem of chemosis and damage, it merely attempts to deal with the problem as it relates to loss of vacuum. Hellenkamp, however, acknowledges that damage does occur from the operation of annular vacuum rings.

The Examiner states, "Both L'Esperance (EP '127) and Hellenkamp teach a device and method as claimed except for the criss-cross passages." *OA July 14, 2006, at page 5.* The criss-cross channels, providing alternating lands and grooves, are fundamental to the present invention, and are not disclosed by the cited references. L'Esperance and Hellenkamp do not disclose means for fixing an eye for surgery other than a hollow annulus and porous membrane. A hollow annulus has specific disadvantages not appreciated by either L'Esperance nor Hellenkamp which are addressed by the present invention. The First Will Affidavit addressed theis extensively. The Second Will Affidavit provides references demonstrating that existing devices are a cause of damage.

The Examiner also asserts that "to discontinue vacuum and reposition the apparatus if it is not centered on the cornea [is obvious], since proper positioning of the corneal flap is critical..." *OA July 14, 2006, at p. 5.* This misses the point. The apparatus and methods of the references cited by the Examiner may actually *prevent* discontinuation of vacuum and repositioning of the apparatus due to the negative effects of using a hollow annulus to apply vacuum, as

explained by the First Will Affidavit. Thus, the Examiner's arguments regarding obviousness actually demonstrate the unobviousness of using a system of criss-cross channels providing alternating lands and grooves.

In addition, L'Esperance and Hellenkamp retain the significant disadvantage that they require lid speculum during most procedures (due to the inherently high profile of the hollow annulus), especially for patients with narrow ocular orbits, and they contain no teachings to indicate a solution. Both Will Affidavits address the problems with lid specula. The Second Will Affidavit addresses Examiner's skepticism on the need for a lid speculum and that the need for lid specula increases the risks of complications. The problems associated with lid specula are the subject of growing concern and more research is being directed toward this problem. *See Second Will Affidavit at ¶¶5 & 14-17.* Patients experience discomfort and the risk of complications such as droopy eye and extra skin layers (similar to calusing) are problematic. Worse is the potential for complications due to the need to cut patients' eyelids back and having to suture them after surgery. Dr. Will also explains that the strain from a patient's eyelids is sometimes enough to dislodge the vacuum fixation device entirely. Thus, there is a need for lid specula when using high-profile vacuum anulus designs such as L'Esperance and Hellenkamp. Dr. Will explains that the criss-cross channels allow the design of a low profile vacuum fixation device able to fit under most patients' lids, obviating the need for lid specula.

Examiner's rejections appear to based on a view that the Applicant is required to prove that the references cited by Examiner are non-functioning, or

that such references must be presumed full proof and without significant drawbacks, in order to claim an invention with improved results over the existing art. The burden lies with the Examiner to demonstrate that Applicant's invention is obvious through citation to record evidence rather than simply relying on conclusory statements that he is "unconvinced." In Examiner's Office Action of June 14, 2007, at p.8, Examiner states that because L'Esperance and other references are patents they are "presumed valid" and therefore L'Esperance's porous membrane does not clog. Respectfully, Examiner misapprehends the difference between patent validity and perfection. The mere fact that a patent is presumed valid does not imply that such a patent solves, perfectly and forever more, all problems associated with the field of art such that no new patentable device may ever issue in the future.

The references accompanying the Second Will Affidavit discuss some of the research now focusing on LASIK complications such as Dry Eye, scleral damage, and other complications caused by vacuum rings. Dr. Will explained that reference to "vacuum ring" in the research refers to anular vacum rings as described in Hellenkamp and Curtin, as these are the industry standard. It is hoped that Examiner, in reviewing these references, will agree that there is a developing consensus that conventional vacuum rings, such as described in Hellenkamp and Curtin, are a source of Dry Eye as well as other problems. Needless to say, there is likely more than one cause of Dry Eye after LASIK, and Dr. Will is not required to disprove the Examiner's thesis in order to establish that his invention reduces potential for this complication, and that a potential source

of the complication is damaged sclera caused by conventional vacuum rings. The purpose of the references is to demonstrate that problems do exist with existing annular vacuum ring designs such as Hellenkamp.

Examiner referenced an article by Benitez-del-Castillo et al, *Decrease in Tear Secretion and Corneal Sensitivity After Laser In Situ Keratomieusis*, CORNEA, vol. 20(1), January 2001 at pp. 30-32 (*see June 14, 2007 OA at pp.7-8*). The reference, a copy of which was provided by Examiner, does not profess to answer all causes of dry eye complications after LASIK , it merely confirms that such complications do indeed occur. Applicant's invention, as explained in the Specification and in Dr. Will's affidavit, seeks to address some of the causes of complications and less than optimal outcomes. Examiner's cited reference does not obviate the different approach that Applicant has taken to solve these problems, nor does it indicate in anyway that vacuum rings do not cause damage, that vacuum rings do not hinder repositioning after application; nor that porous membranes such as described in L'Esperence do not clog. Nor does Examiner's cited reference indicate that lid specula are not required when using high profile vacuum anulus designs.

The difficulty in cleaning is discussed as a general hindrance which can reduce the patient turnover rate. *See Hellenkamp, col. 3, l. 45 – col. 4, l. 12.* The same difficulties with clogging and effective cleaning described in Hellenkamp are magnified in a porous membrane as taught by L'Esperance. Additional drawbacks include higher risk of patient cross-contamination with viral, bacterial and prion material. *See First Affidavit of Will* ¶ *5.h*. The present

invention provides a relatively smooth and impermeable surface with shallow cross-connected channels which are more easily cleaned using conventional methods, thereby extending the life of the apparatus. The cross-connection prevents loss of vacuum from occlusion of any single channel due to buildup.

Dr. Will also explains that the criss-cross channel design is specifically what permits achievement of a low profile, obviating the need for a lid speculum in most cases. Additionally, the hollow annulus designs inherent to L'Esperance and Hellenkamp require the use of a lid speculum on patients with narrow ocular orbits. The use of lid specula causes undesired negative side effects which have been documented, and are an ever increasing problem as procedures such as LASIK become more widespread.

Dr. Will's First and Second Affidavits specifically address the complications caused by conventional hollow annulus apparatus, which are reduced or eliminated by the design of his invention. See First Will Affidavit at ¶¶ 4, 8-9; Second Will Affidavit at ¶¶ 10, 14-17. The use of criss-cross channels with alternating lands and grooves in the present invention avoids the need for lid speculum even in patients with narrow orbits because it allows a lower profile device. The Examiner has failed to point to any reference which teaches criss-cross vacuum channels, creating a low profile apparatus which can fit underneath the eyelids, obviating the need for a lid speculum during surgery. All of the art cited by Examiner relies upon an annular design necessitating a vault, with the exception of Ruiz, newly asserted by Examiner, which does not teach the use of a vacuum fixation apparatus at all and so does not support the

rejection.

Applicant does not argue that the prior art cited lacks utility or is non-functional, but the present invention provides unobvious improvements over the cited references which achieve greater accuracy and less discomfort from patients, while making laser keratome procedures more economical for practitioners.

Further, if the Examiner relies on personal knowledge to assert that:

(1) L'Esperance and Hellenkamp are not subject to clogging or occlusion;

(2) neither L'Esperance nor Hellenkamp cause damage to the cornea/conjunctiva surface when vacuum is applied and removed;

(3) high profile vacuum rings such as L'Esperence and Hellenkamp do not require lid specula; and,

(3) that use of high profile hollow annular rings as taught by the Examiner's cited references does not cause complications and discomfort to patients;

then the Examiner is required to provide an affidavit explaining the basis of such knowledge. *See* MPEP 2144.03(A) [R-1], which states:

> "It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."). While the court explained

that, "as an administrative tribunal the Board clearly has expertise in the subject matter over which it exercises jurisdiction," it made clear that such "expertise may provide sufficient support for conclusions [only] as to peripheral issues." *Id.* at 1385-86, 59 USPQ2d at 1697. As the court held in *Zurko*, an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. *Id.* at 1385, 59 USPQ2d at 1697. See also *In re Lee*, 277 F.3d 1338, 1344-45, 61 USPQ2d 1430, 1434-35 (Fed. Cir. 2002) (In reversing the Board's decision, the court stated "'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation... The board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies."

Further, "While 'official notice' may be relied on, these circumstances should be rare when an application is under final rejection..." MPEP 2144.03(A) [R-1].

> "It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21. See also *In re Grose*, 592 F.2d 1161, 1167-68, 201 USPQ 57, 63 (CCPA 1979)"

MPEP 2144.03(A) (emphasis original). "If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. *See* 37 C.F.R. 1.104(d)(2)." MPEP 2144.03(C) [R-1]. Furthermore, Section 103 requires analysis of a claimed invention as a whole:

> "Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness."

The Gillette Co. v. S.C. Johnson & Son Inc., 16 USPQ2d 1923 (Fed. Cir. 1990).

The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. at 17-18; Miles Lab., Inc. v. Shandon Inc., 27 USPQ2d 1123, 1128 (Fed. Cir. 1993). The Second Will Affidavit accompanying this RCE provides objective evidence of the difference between the prior art and the claimed invention which must be credited. Regarding the use of criss-cross channels, incorporated into all claims through independent claims 1, 11 and 22, no references cited by the Examiner include criss-cross channels. The use of criss-cross channels minimizes distortion of the eye lens which causes less than optimal correction to patients' vision. The criss-cross channels prevent or minimize damage to the cornea, sclera and conjunctiva which has been a documented problem in LASIK and other keratome procedures using apparatus such as relied upon by the Examiner. The criss-cross channels permit a low-profile device which can fit under patients' eye lids, obviating the need for a lid speculum, thereby reducing complications in patient recovery and reducing obstructions during surgery. These complications are especially relevant for patients with narrow ocular orbits. Dr. Will's Affidavits also provide citation to references which provide objective evidence to back up his explanations of the differences and advantages of his invention over the prior art demonstrating the unobviousness of the claims. *See First Affidavit of. Will ¶¶ 7-8; Second Will*

Affidavit ¶¶*6-11*.

Moreover, "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 230 USPQ 416 (Fed. Cir. 1986). The Examiner's rejections amount to using that which Dr. Will teaches in his patent against him by selectively choosing elements of several references and combining them without explanation of objective evidence which would lead a person to combine the references - at which point the Examiner argues it would be obvious to further modify the combined elements of the various references to achieve the claimed invention by adding criss-cross vacuum channels, again without any suggestion, teaching or motivation or objective evidence. This is exactly the type of hindsight analysis that is so often rejected in court decisions.

Both Hellenkamp and L'Esperance teach vacuum rings with annular vaults requiring the use of lid specula causing greater discomfort for patients. *See Affidavit of Dr. Will at ¶ 8.* L'Esperance '172 (cited by Examiner), which is a continuation-in-part of Application 891,285 issued as L'Esperance '148 (also cited by Examiner), specifically teaches the requirement of using a lid speculum and can therefore be viewed as teaching away from apparatus and methods which do not require such. *See L'Esperance '172, col.3, ll.50-59.* "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in

the reference; or would be led in a direction divergent from the path that was taken by the applicant." Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 45 USPQ2d 1977 (Fed. Cir. 1998). *See also* The Dow Chemical Co. v. U.S.,18 USPQ2d 1657 (Ct. Cl. 1990). The use of criss-crossed channels with alternating lands and grooves, a recited element in all claims of the present invention, eliminates the need for annular vaults thereby creating a lower profile device. This lower profile eliminates the need for a lid speculum in most cases, and is more comfortable for patients, especially those with narrow or tight lid openings. This fundamentally distinguishes the present claims from L'Esperance.

Examiner incorrectly states that there is no disclosure in the Application relating to holding the corneal surface flat, without displacement into the criss-cross vacuum channels. The Specification at page 6, lines 12-20, states:

> "When placed on the eye, with the contact portion **14** contacting directly upon the eye and encircling the cornea, the criss-crossing channels **16** are upon the eye globe conjunctiva. Vacuum port **18** communicates with channels **16** such that vacuum pressure exerted at the vacuum port **18** creates vacuum pressure in the criss-crossing channels **16**, *sucking the eye globe conjunctiva attached to the sclera flush against the contact portion **14***. This fixates the eye.. The criss-crossing channels **16** work to oppose the suction created by each other, such that *the eye glove conjunctiva attached to the sclera, is spread taut between the channels **16**, instead of being sucked upon into a particular channel*."

Specification, page 6, lines 12-20 (emphasis added). Further, the Specification's "Summary of the Invention", at page 4, lines 11-21, recites decreased trauma to the ocular surface and the ability to more easily reposition the fixation device after vacuum has once been applied as specific advantages of the present

invention. Further, Dr. Will's accompanying Affidavit for further evidence in this regard. In contrast, the Hellenkamp reference relied on by the Examiner specifically acknowledges that the cornea is displaced into the hollow vacuum ring to contact the surface of the vacuum enhancer. *Hellenkamp at col.9, ll. 23-43.* Conversely, the Examiner provided no record evidence to support his incorrect factual assertion that the present invention does not draw the cornea surface to contact against the flat land between the criss-cross channels, rather than into the channels themselves, as claimed and described.

Additionally, the use of criss-cross channels (a recited element of each claim) avoids the problem of clogging which porous surfaces (such as taught in L'Esperance) are subject to. The use of channels also permits a lower profile than devices using a porous surface can achieve because there is no need for the vacuum annulus above the porous surface (as taught in L'Esperance). Thus, the present invention provides unobvious solutions to the problems inherent in existing apparatus and methods.

Examiner incorrectly stated that "with regard to Hellenkamp, applicant theorizes a problem with the reference, but does not associate it with any particular structure of the device." The First Will Affidavit directly addresses the inherent problems with existing devices and methods and the specific structures and methods which solve these problems. The Second Will Affidavit addresses this in further detail, and provides references in support. Applicant has made clear that a significant disadvantage of existing designs such as Hellenkamp, Curtin, and others is that they rely on a hollow annular ring to apply vacuum,

which causes the cornea surface to displace into the vault of the ring. The vacuum enhancer taught by Hellenkamp reduces this problem in certain respects, but does not eliminate it. Applicant has also explained that the vault – inherent in the design of existing hollow annular rings, including Hellenkamp, Curtin and L'Esperance – creates the need for a lid speculum during procedures, which is generally eliminated by the low profile of the criss-cross channel design which is recited in all claims of the present invention. Applicant, by pointing out these specific drawbacks of existing apparatus and methods, does not argue that these references are inoperative or invalid, but merely that they are not perfect solutions. The present invention represents a significant improvement over existing apparatus and methods in many respects. The Examiner incorrectly implies that by claiming improvement over the existing art Applicant must thereby prove the existing art lacks utility. The existing art does what it does - the present invention improves upon this.

Examiner describes the pores of L'Esperance as lands and grooves but cites no support for this. *See June 14, 2007 OA at pp. 10-11.* A porous surface would necessarily be considered smooth, lacking lands and grooves. Referring to L'Esperance's porous surface as lands and grooves extrapolates the minimal teachings of L'Esperance much too far. L'Esperance teaches a porous, air-permeable membrane. This is not equivalent to criss-crossing channels creating lands and grooves. L'Esperance applies suction through a porous membrane via an annular chamber above the porous membrane. *See L'Esperance '127 at col.4, ll.26-34.* This is the only method taught by L'Esperance '127 and its

related applications. *See e.g. L'Esperance, Jr. '148 (also cited by Examiner) and L'Esperance, U.S. 4,665,913, incorporated by reference into L'Esperance '148.*

Examiner is correct to note that the porous surface of L'Esperance distributes vacuum over its surface to improve stability. However, such porous surfaces are subject to clogging. All porous materials are subject to clogging, a simple fact of nature which Dr. Will has confirmed with real-world experience in performing thousands of eye surgeries. Examiner has cited nothing in L'Esperance or any other reference suggesting special properties which render L'Esperance's porous membrane not subject to clogging. Rather than placing the burden on Applicant to find a reference describing L'Esperance's shortcomings, the burden rests with Examiner to cite a reference explaining how Dr. Will's description of L'Esperance's tendency to clog is not correct. The fact that L'Esperance does not address this problem does not render it inapplicable – L'Esperance was primarily focused on issues not related to the eye fixation methods. Hellenkamp, and Dr. Will's Affidavit, both address significant problems with buildup of mucous and other debris within vacuum channels leading to occlusion. Examiner fails to explain how the pores of L'Esperance are magically free of clogging issues whereas the full bore annular vacuum rings of Hellenkamp are subject to occlusion. Dr. Will stated in his affidavit that based on his actual experience conducting surgeries that the porous membrane of L'Esperance would be subject to clogging. *See First Will Affidavit at ¶ 9.* Moreover, as noted in the Second Will Affidavit, he has been performing LASIK procedures for over 17 years and is not familiar with any fixation device which

utilizes the porous membrane described in L'Esperence - despite the widespread use of laser ablation procedures. This is a strong indication that the porous membrane is not optimal.

Examiner at p.6 (*see June 14, 2007 OA*) states, "It is not clear to the examiner why" a low profile device obviates the need for a lid speculum. The First Will Affidavit explains that devices relying on a vacuum annulus require use of a lid speculum. The Second Will Affidavit provides further explanation. Dr. Will has performed thousands of eye surgeries. If Examiner does not have a reference which contradicts Dr. Will's affidavit then it should be taken at face value. Respectfully, Applicant submits that if the Examiner disputes facts in Dr. Will's affidavit then the burden rests on Examiner to prove his contentions based on references which can be made part of the record, so that Applicant may respond and reviewing bodies can review the evidence. Moreover, regardless of whether Examiner was able to review the articles referenced by Dr. Will in his affidavit, Dr. Will has stated that based on his direct experience, that of his staff, and his research, existing devices operating similar to L'Esperance and Hellenkamp face limitations which the present invention addresses. Applicant submits that the Examiner failed to cite reliable references in the record.

Examiner at p.7 (*see June 14, 2007 OA*) states that L'Esperance's membrane forms only "a portion" of the device but extends beyond the annular chamber and so would fit under the eye lid. Applicant points out that this extending lip does not convey vacuum as there is no vacuum source above it. A membrane would conduct vacuum only through its plane, not laterally. Thus the

annular chamber necessarily is concurrent in area with the vacuum-affected surface of the membrane. The annular access provided for surgical access is inside the inner diameter of the vacuum annulus. By contrast, as pointed out in Dr. Will's affidavit and the specification, the criss-crossing channels extend from the annulus provided for surgical access outward, with no vacuum annulus above them. The criss-cross channels therefore provide an inherently lower profile. Again, neither L'Esperance nor Applicant's figures are drawn to scale so Examiner's attempts to measure proportions is inappropriate. One can observe the structures and note that there is indeed, necessarily, a vacuum annulus extending vertically above the membrane of L'Esperance (see Fig. 1, #10, 11, 12 & col. col. 4 ll. 28-35), while the vacuum channels of claims 1, 11 and 12 extend laterally with no vertical vacuum annulus rising above, allowing a narrow profile for an eyelid to fit over (see Fig. 4).

Examiner at page 5 (*see June 14, 2007 OA*) equates the vacuum distributor inside the suction ring of Hellenkamp equates to the distributed lands and grooves created by the criss-crossing channels of claims 1, 11 and 12. *See June 14, 2007 OA.* The problem with Examiner's evaluation is that in Hellenkamp the sclera does not contact the surface of the insert *until it has been sucked into the annulus of the vacuum ring* – thus substantially all of the damage has already been done. Nowhere does Hellenkamp teach, nor do the drawings of Hellenkamp illustrate, a flush-mounted land and groove contact surface. Hellenkamp never contemplated a solution involving anything other than a vacuum ring. Moreover, Hellenkamp merely attempts to distribute vacuum more

evenly – but this is only a partial solution. The real damage is caused by displacement into the vacuum ring itself, which Hellenkamp does not prevent. L'Esperance, while able to prevent displacement has the potential of causing the opposite problem. If the pores of L'Esperence clog then either of two outcomes is likely. Either vacuum hold will be lost, allowing the fixation apparatus to move or separate completely from the cornea, or, the clogged pores will lock the vacuum between the membrane surface and the conjunctiva with no way to break the vacuum. The result is that the apparatus must be separated under vacuum potentially tearing the sclera. Either outcome is undesirable. The criss-cross channels of Applicant's invention prevent displacement into a annular vacuum ring without the danger of clogging created by L'Esperance's membrane.

The lands of the criss-crossing channels provide the contact surface without being drawn into an annular ring. The vacuum channels are on opposing sides of any given land such that they act against one another to pull the sclera against the lands between rather than displacing into the channels themselves.

Claims 2 and 13.

Dependent Claims 2 and 13 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp in combination with Curtin. Traversal with respect to L'Esperance or Hellenkamp is reasserted regarding independent claims 1, 11 and 12 and further with regard to their combination with Curtin, which teaches a conventional hollow annular ring. *Curtin, col.5, ll. 46-51.*

The Examiner asserts that "Curtin teaches the use of adjustment arms on eye fixation devices." *OA July 14, 2006, at p.5.* Applicant respectfully disagrees.

Curtin specifically teaches that the rigid vacuum tube 128 holds annular ring 124 stationary over an eyeball, at which point the patient is provided a target to focus on which aligns the eye to the apparatus. Vacuum is applied to annular ring 124 which then "locks the ring arrangement 122 on the patient's eye when the patient's visual axis is aligned with the target." *Curtin, col.6, ll. 1-8; col. 7, ll. 29-39 & 63-68.* Curtin does not, alone nor in combination with other references cited, teach or suggest the use of adjustment arms connected to an eye fixation apparatus which permit adjustment of the apparatus to the eyeball prior to fixation, rather than having the eyeball align itself to a vacuum ring. Thus Curtin teaches exactly the opposite methodology of the current invention recited in claims 2, 13 and 22, which renders it less optimal than the current invention.

Dr. Will, in the First Will Affidavit, notes several advantages from the use of adjustment arms. *See First Will Affidavit ¶ 10.c.* Maneuvering the device is easier, and there is less chance that inadvertent contact will scratch the conjunctival surface or cause contamination. While the single adjustment arm of Curtin may have 3-D adjustment capability as argued by Examiner, such capability does not equate to the ease of use provided by the arms of the present invention which would allow a surgeon to grip the arms with each hand while sighting through the annular access hole with a sighting device, rather than the cumbersome apparatus described in Curtin. A person of skill in the art would not see the combination of Curtin with L'Esperance and/or Hellenkamp as teaching the combination of elements of claims 2 and 13.

Claims 3, 4, 7, 8, 14, 15, 18 and 19

Dependent Claims 3, 4, 7, 8, 14, 15, 18 and 19 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp in combination with Curtin and/or Clark et al, and further with respect to Ruiz. (The Examiner had previously cited Ruiz, *see April 11, 2006 OA*, but while not repeating the rejection with Ruiz did not explicitly withdraw it either.)

Examiner incorrectly states that "Clark et al teach employing X- and Y-axis adjustment mechanisms on eye fixation devices." *See June 14, 2007 OA at p.15.* Applicant respectfully disagrees. Applicant has not claimed the concept of X-Y adjustment, but a particular apparatus and method of lateral and cross-lateral position adjustment integrated into an eye fixation apparatus for use during surgical procedures. Clark is not directed to the *positioning* of surgical devices *during surgery*. The adjustment taught by Clark relates to adjusting the platform of a microscope set upon a stable base, away from any surgical procedure, so as to permit the proper depth setting of a microkeratome blade to be used in surgery. Clark, even in combination with L'Esperance and Hellenkamp, does not teach or suggest the elements of translation guide members adjustably connected to an eye fixation apparatus during surgery, nor the additional elements of translation rods with adjustment knobs to provide fine control.

Examiner's additional reliance on Ruiz does not disclose the elements of the claim either. Ruiz teaches a geared cutting blade on a base which lacks the ability to fix the eye in space, and so still fails to disclose, even in combination, all

of the elements of the rejected claims. Ruiz does not disclose a translation member "adjustably connected" to an eye fixation apparatus. The blade guide of Ruiz allows for movement but not adjustment. Ruiz does not teach the use of a threaded guide rod and adjustment knob for adjusting position. Nor does Ruiz teach the use of a second translation guide member non-parallel to a first translation guide member to permit X-Y adjustments.

Reference to Ruiz, Figure 10, also demonstrates the type of lens distortion created by existing apparatus and methods which the present invention is specifically designed to avoid. The Examiner has not established a prima facie case of obviousness under Section 103(a).

As Dr. Will's Affidavit makes clear, the ability to adjust the fixation apparatus to the eyeball, rather than vice versa, provides for better adjustment and concentration properties during laser procedures. This adjustment capability is enhanced by the addition of lateral translation members directly to the eye fixation apparatus. Translation guide rods with knob adjusters allow precise adjustments while requiring less manual dexterity than current apparatus and methods. The translation guide rods also prevent further distortion of the eyeball caused by forcing the eyeball into alignment with the surgical apparatus.

Applicant understands and appreciates Examiner's explanation of how adjustment screws operate, but this does not render the claims obvious. (Nor does Examiner's discussion render the claims invalid as lacking enablement, which seems to be implied by the Examiner.) The statement Examiner refers to is at paragraph 11 of Dr. Will's affidavit, where he refers to the fact that

seemingly minor changes in apparatus and methods can actually achieve significant results in surgical procedures where "adjustments in the sub-micron range" can alter outcomes. The reference was to all of the differences over the prior art in the previous ten paragraphs. Thus, the reductions in eye deformity, intraocular pressure variations, reductions in hydration variation of the cornea, improved positioning capabilities, improved re-positioning capabilities, improved adjustment capabilities, and lessened complications achieved by the apparatus and methods claimed, all lead to significantly improved outcomes individually and cumulatively. The point was that improvements over prior art devices in positioning or focusing LASIK apparatus may, in some cases, only be in the sub-micron range, but even such small *improvements* can be significant.

In addition, Dr. Will's affidavit makes clear the differences between the present invention and the asserted references. X-Y adjustment ability and the use of docking screws for setting and adjusting surgical apparatus prevents further distortion of the eyeball caused by forcing the eyeball to alignment with the apparatus, rather than vice versa. It also eliminates the need for expensive and complicated software to adjust for laser offset. The claims are unobvious.

Claims 5, 6, 9, 10, 16, 17, 18 and 19

Dependent Claims 5, 6, 9, 10, 16, 17, 18 and 19 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp and Curtin in combination with Clark et al, and further in regard to Ruiz and/or to U.S. 6,613,061 Olson. Olson was newly cited by Examiner in the Office Action, but Olson does not add anything to the teachings of the other cited references.

Olson uses a conventional anular vacuum ring - the same as Hellenkamp, Curtin and Clark. *See Olson, col.1, lines 55-60; Fig.1 #3.* Applicant does not claim docking screws in isolation, but the claims as a whole incorporating docking screws into a device utilizing criss-cross vacuum channels in a low profile device are novel and unobvious. Examiner appears to be picking and choosing individual elements without addressing the claims as a whole, which amounts to hindsight reconstruction utilizing the Applicant's disclosure against him. None of the cited references, even in combination, teach all the elements of the rejected claims. The dependent claims listed incorporate all of the elements of the claims from which they depend.

The cited references simply do not disclose the elements of the present invention. Applicant reiterates the discussion above, relating to the lack of teaching of first and second translation guide members in the cited references. The references, even in combination, do not teach employing x- and y-axis adjustment mechanisms movably connected to eye fixation devices during surgery, as discussed above. Clark et al does not teach the use of docking screws to tighten against objects inserted into the cylindrical space formed by the first (or second) annular translation guide members. Clark teaches only bench alignment of cutting devices, which devices are then used in ophthalmic surgery. Examiner's additional reliance on Ruiz does not disclose the elements of the claim either. Ruiz teaches a geared cutting blade on a base which lacks the ability to fix the eye in space, and so still fails to disclose, even in combination, all of the elements of the rejected claims. Ruiz does not disclose use of docking

screws to tighten against objects in the annulus, especially considering Ruiz teaches a movable cutting blade. Nor does Ruiz teach the use of a second translation guide member non-parallel to a first translation guide member to permit X-Y adjustments with a docking screw. The Examiner has not established a prima facie case of obviousness under Section 103(a).

The references, even in combination, teach the use of docking screws to dock surgical devices to translation guide members at all, much less translation guide members which are adjustably connected to an eye fixation apparatus during surgery. The addition of docking screws to dock surgical apparatus, such as lasers or optical cones, directly to the eye fixation apparatus ensures even more precise alignment to achieve superior concentration properties in laser procedures. *See Second Will Affidavit.*

Claim 22

Examiner rejected claim 22 under § 103(a) based on a combination of L'Esperance or Hellenkamp in combination with Curtin and Clark et al, and further in combination with Olson. Claim 22 includes all of the elements of claims 1-10 but explicitly recites the limitation "wherein the eye fixation portion has a low profile convex bottom contact portion..." and "...is substantially narrow so as to fit under the eye lid of a patient without the use of a lid speculum." Independent Claim 22 stands on its own, but the arguments traversing rejections of apparatus claims 1-10 and method claims 11-21 are equally valid regarding the non-obviousness of apparatus claim 22. The Specification, at page 4, lines 11-14, describes a feature of the invention that "(1) functions without the need for a lid

speculum; (a) low profile fits comfortably under the lids; (b) can more easily be used on patients with "tight lids" which are common to some races..." The First Will Affidavit discussed the greater susceptability of persons with narrow ocular orbits such as patients of Asian descent to complications such as Dry Eye, based on professional experience, as well as professional literature. The Second Will Affidavit discusses this problem in greater detail. *See Second Will Affidavit ¶¶9 & 14-17.* Exhibit 5 to the Second Will Affidavit describes a clinical study confirming that patients of Asian descent experience higher incidences of certain complications relating to smaller ocular orbits, including Dry Eye. The low profile design of the present invention, made possible by the criss-cross vacuum channels, addresses this problem by reducting the need for lid specula and reducing the rise in IOP caused by (intentionally so) conventional vacuum rings such as taught in Hellenkamp, Curtin, Clark and Olson.

Applicant reasserts each of the arguments regarding rejections of claims 1-21, above, in regard to Claim 22. None of the cited references, even in combination, discloses all of the elements of claim 22 much less discloses the combination of the elements. Specifically, none of the references discloses a low profile fixation portion with criss-cross channels, first and second translation guide members with adjustment rods and knobs, docking screws in the first and second translation guide members, wherein the profile of the fixation portion – i.e. the structure containing the vacuum channels – is low enough to fit under the eye lid of a patient to obviate the need for a lid speculum.

CONCLUSION

The present invention improves the precision (and reliability) of positioning devices for keratome and LASIK procedures, reduces damage to the conjunctival tissue, and makes the procedure more economical through the use of apparatus and methods which are more amenable to cleaning and reuse. The rejections are respectfully traversed as to all claims. It is requested that the rejections be withdrawn. The present invention specifically addresses the limitations of apparatus and methods such as cited by Examiner. It is important to note that ophthalmic surgery is an art where seemingly minor changes have significant impact. For the foregoing reasons, reconsideration and allowance of claims 1 through 22 of the application as amended is requested.

The Examiner is encouraged to telephone the undersigned at (360) 750-9931 if it appears that an interview would be helpful in advancing the case. The Applicant respectfully submits that the rejection of the pending claims must be withdrawn, and that this application is in condition for allowance for all claims pending. Such is earnestly requested.

Respectfully submitted,

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